AMCP | Academy of Managed Care Pharmacy®

September 28, 2015

The Honorable Michael Callton
Chair
Health Policy Committee
Michigan House of Representatives
Anderson House Office Building, N-1191
Lansing, MI 48933

RE: Substitute for House Bill No. 4437 (Draft 2)

Dear Representative Callton:

The Academy of Managed Care Pharmacy (AMCP) wrote to you in June concerning our opposition to certain provisions in House Bill 4437 because those provisions would place unnecessary restrictions on the substitution of biosimilars determined to be interchangeable with reference biologic products by the U.S. Food and Drug Administration (FDA). Since that time, we have become aware of the above referenced substitute for House Bill No. 4437.

AMCP is a national professional association of pharmacists and other health care practitioners including 165 members in Michigan who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's nearly 7,000 members develop and provide a diversified range of clinical, educational, and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

AMCP believes that the above referenced substitute addresses one of our major concerns with House Bill 4437 as introduced. Specifically, Section 17755 (6) required the pharmacist to notify the prescriber before dispensing a biosimilar product. It is our understanding now that is the current law for other substitutions in Michigan, so this legislation does not add an additional requirement for this category of drugs. Also Section 1775 (6) has been amended to clarify that if the pharmacist dispenses an interchangeable biological product, the pharmacist does not have to notify the prescriber prior to dispensing. AMCP supports that amendment.

That amendment is consistent with the Biologics Price Competition and Innovation Act (BPCIA) definition of an interchangeable: "the term 'interchangeable' or 'interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product." [42 U.S.C. 262 (i)(3)].

100 North Pitt Street | Suite 400
Alexandria, VA 22314
800 827 2627 | 703 683 8416
Fax 703 683 8417
www.amcp.org

We support the Substitute for House Bill No. 4437 (draft). It is consistent with the intent of Congress when it passed the BPCIA to foster competition and innovation in order to improve access and affordability for American patients. This category of drugs will bring value to your constituents as patients and payers by enhancing access to FDA approved, safe and effective, lower cost medications.

We appreciate the opportunity to share our views on House Bill 4437. If you have questions, you may contact our local advocacy leader, Cheryl Kaltz of Northville, MI, at (586) 904-0820 or cheryl.kaltz@att.net. You may also contact AMCP's Director of Legislative Affairs, Reginia Benjamin, at (703) 683-8416 or rbenjamin@amcp.org.

Sincerely,

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

cc: Members of the House Health Policy Committee